UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,806	02/18/2004	Jacob Zabara	200477.00002	1496

21324 7590 06/07/2007

HAHN LOESER & PARKS, LLP
One GOJO Plaza
Suite 300
AKRON, OH 44311-1076

EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	**PAPER NUMBER**
3735	

NOTIFICATION DATE	DELIVERY MODE
06/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	10/780,806	ZABARA, JACOB	
	Examiner	Art Unit	
	Sara Lustusky	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29,31-70,72,76-78* is/are rejected.

7)☒ Claim(s) *30,71 and 73-75* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/01/05; 04/01/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9-15, 17-21, 50, 52, 64, 69 and 77-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerber et al. (US 2004/0049240 A1).

Gerber et al. teaches a therapeutic method for treating a medical condition in a patient, said method comprising diagnosing a medical condition of a patient, administering an electric nerve stimulation (ENS) therapy to a first body location of said patient, and administering a magnetic stimulation (MS) therapy to a second body location of said patient (as described in the abstract and in paragraphs [0014]-[0016]); wherein said MS therapy is applied to tissue remote from the brain of the patient (as described in paragraph [0016]); wherein said magnetic stimulation (MS) therapy is administered to said patient after said electric nerve stimulation (ENS) therapy is administered to said patient; wherein said magnetic stimulation (MS) therapy administered to said patient before said electric nerve stimulation (ENS) technique is administered to said patient; said method further comprising temporally alternating said administration of said electric nerve stimulation (ENS) therapy and said administration

of said magnetic stimulation (MS) therapy a plurality of time; wherein said electric nerve stimulation (ENS) therapy and said magnetic stimulation (MS) therapy are administered simultaneously (as described in paragraphs [0034] and [0044]-[0047]), wherein said electric nerve stimulation (ENS) therapy is administered until a desired clinical outcome is achieved, followed by said administering of said magnetic stimulation (MS) therapy for enhanced effectiveness, wherein said magnetic stimulation (MS) therapy is administered until a desired clinical outcome is achieved, followed by said administering of said electric nerve stimulation (ENS) therapy for enhanced effectiveness, wherein said magnetic field comprises a pulsed magnetic field, wherein said magnetic field comprises an alternating magnetic field, wherein said magnetic field comprises a steady magnetic field (as described in paragraphs [0016] and [0047]), wherein said selectively adapting said at least one parameter of said magnetic field results in changing said physiological response such that said change in said physiological response indicates a reduction in said symptoms, wherein said at least one parameter of said magnetic field comprises a pulse width, a pulse repetition frequency, a magnetic intensity, and an orientation, wherein said method using a system comprising a magnetic stimulation (MS) subsystem to generate a pulsed current waveform to produce a pulsed magnetic field to stimulate a first region within the brain of said patient, an electric nerve stimulation (ENS) subsystem to generate electric signals to stimulate a second region within the brain of said patient (wherein stimulating a portion of the body therefore stimulates a portion of the brain), wherein said electric nerve stimulation (ENS) and said magnetic stimulation (MS) therapy changes a polarization of synaptic membrane in a

nuclei or center of the brain of the patient in view of the ways signals travel from the body to the brain, and wherein focusing of said pulsed magnetic field is aided by induced electric charges that occur naturally within said brain of said patient at synaptic membranes, said method further comprising a computer-based switching subsystem or a controller coupled to said magnetic stimulation (MS) subsystem and said electric nerve stimulation (ENS) subsystem to select at least one of said magnetic stimulation (MS) subsystem and said electric nerve stimulation (ENS) subsystem for stimulation of the brain of the patient (as described in paragraphs [0035]-[0041]), wherein said pulsed current waveform comprises one of monophasic pulses, symmetric biphasic pulses and exponential decay biphasic pulses (as described in paragraph [0047]), wherein magnetic stimulation acts on pathological or dysfunctional tissue or organs of the body to cause an enhanced polarization effect to control or prevent any illness affecting the body (as described in the abstract), wherein magnetic stimulation aids electrical nerve stimulation (ENS) by acting on the brain or dysfunctional tissues or organs of the body to cause an enhanced polarization effect to control or prevent any illness affecting the brain or body (as described in the abstract).

Claims 1, 3-4, 6-10, 12-20, 22-24, 26-29, 31-41, 43-48, 50-51, 53-55, 57-58, 61-62, 64, 69-70 and 76-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Gliner (US 2003/0074032 A1).

Gliner teacher a therapeutic method for treating a medical condition in a patient, said method comprising diagnosing a medical condition of a patient, administering an electric nerve stimulation (ENS) therapy to a first body location of said patient, and

administering a magnetic stimulation (MS) therapy to a second body location of said patient (as described in the abstract and in paragraph [0006]-[0008], [0023] and [0028]), wherein said ENS therapy comprises cranial nerve stimulation, wherein said MS therapy comprises transcranial magnetic stimulation (as described in paragraph [0027]), wherein said step of administering a MS therapy comprises applying a magnetic field to a pre-selected synaptic region of the brain of the patient, monitoring a physiological response associated with said application of said magnetic field, and selectively adapting at least one parameter of said magnetic field in response to said monitored physiological response (as described in paragraphs [0023]-[0036]), wherein said first body location comprises a first set of nerves in the brain and said second body location comprises a second set of nerves in the brain, wherein said ENS therapy and said MS therapy may both be administered to the same set of nerves in the brain, wherein said ENS and MS therapy induce nerve responses in the brain and thus changes a polarization of synaptic membranes in a nuclei or center of the brain of the patient (as was commonly known in the art at the time of the invention and is described in paragraphs [0006]-[0009]), wherein said MS therapy may be administered to said patient before, after or during said ENS therapy and may be repeatedly administered to said patient (as described in paragraphs [0008], [0020]-[0023], [0028] and [0030]), wherein said MS therapy is administered to nuclear synaptic areas including cell bodies, dendrites, and pre-synaptic terminals where a membrane potential exists and an action potential does not exist (all of which are within the brain), wherein said magnetic field comprises a pulsed or alternating magnetic field (as described in paragraph [0027]) (as

seen in Figure 2), wherein said physiological response includes changes in electroencephalogram (EEG) activity of said brain (as described in paragraphs [0034]-[0036]), wherein said selectively adapting said at least one parameter of said magnetic field results in changing said physiological response such that said change in said physiological response indicates a reduction in said symptoms (as described in paragraphs [0003]-[0005] and [0045]), wherein said at least one parameter of said magnetic field comprises a pulse width, a pulse repetition frequency, a magnetic intensity and an orientation (as described in paragraph [0047]), wherein said step of monitoring said physiological response comprises contacting at least one electrode on the scalp of said patient to monitor EEG changes of said brain, wherein said step of applying a magnetic field comprises producing a current within said brain with or without generating a motor seizure and/or an EEG seizure in said patient, wherein said motor seizure is prevented by limiting said application of said magnetic field so as not to reach a motor area of said brain, wherein said motor area of said brain inherently comprises a motor cortex of said brain which would control a motor seizure, wherein said step of applying a magnetic field comprises producing a current within areas of said brain that do not include motor centers of said brain, wherein said step of applying a magnetic field comprises providing at least one magnetic coil for producing said magnetic field (as described in paragraph [0027]), wherein said step of applying a magnetic field comprises providing at least one magnetic coil connected to a generator which inherently comprises capacitors, switching elements and sensing elements (as described in paragraphs [0025], [0031] and [0037]), wherein said generator is

connected to an electrical power source, wherein said step of applying a magnetic field comprises concentrating said magnetic field in certain brain synaptic regions by selectively orienting at least one magnetic coil with respect to said certain brain synaptic regions, wherein said step of applying a magnetic field comprises providing a positively or negatively directed induced current (a result of an alternating current) to a produce a response in the nerves of the brain which comprise both depolarization and hyperpolarization phases, wherein said hyperpolarization will cause a decrease in EEG frequency within said certain synaptic regions of said brain and wherein said depolarization will cause an increase in EEG frequency within said certain synaptic regions of said brain (as described in paragraphs [0006]-[0010]), wherein said step of inducing a current produces synaptic polarization changes that do not cause a nerve-firing threshold to be reached in certain synaptic regions, wherein said MS and ENS therapy is applied with a respective MS subsystem and ENS subsystem, wherein said control system comprises a computer-based switching subsystem coupled to said MS subsystem and said ENS subsystem to select at least one of said MS subsystem and said ENS subsystem for stimulation of the brain of the patient (as described in paragraph [0025]), wherein said computer-based switching subsystem inherently comprises switches and storage capacitors having an electrical input and an electrical output, an electrical energy source coupled to said electrical input of said configuration and at least one magnetic coil coupled to said electrical output of said configuration as described in paragraphs [0025]-[0027]), further comprising a monitor subsystem to monitor a physiological response of the brain of the patient to said electric signals

and/or said pulsed magnetic field (as described in paragraphs [0031]-[0033]), wherein said pulsed magnetic field is monophasic, biphasic or polyphasic damped field and therefore produces a monophasic, biphasic or polyphasic damped induced current within said first region of the brain of said patient (as described in paragraph [0024]), wherein said at least one magnetic coil is coupled to said configuration via at least one flexible high-power cable (as described in paragraph [0043]), wherein said pulsed magnetic field produces synaptic polarizations in different regions of said brain of said patient depending on at least a size of said magnetic coil, a geometry of said magnetic coil with respect to said patient, and a magnetic field strength of said pulsed magnetic field, wherein focusing of said pulsed magnetic field is aided by induced electric charges that occur naturally within said brain of said patient at synaptic membranes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 7, 9-10, 16, 27 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (US 6356788 B2) in view of Epstein et al. (US 6132361 A).

Boveja teaches a therapeutic method for treating a medical condition in a patient, said method comprising diagnosing a medical condition of a patient and administering an electric nerve stimulation (ENS) therapy to a first body location of said patient,

wherein said electrical nerve stimulation (ENS) therapy comprises vagus nerve stimulation and therefore cranial nerve stimulation (as described in lines 38-46 of column 1), wherein said medical condition is a neuropsychiatric disorder (as described in the abstract and in lines 43-47 of column 8), wherein said first body location comprises a first set of nerves in the brain (as described in lines 25-39 of column 2 and lines 49-65 of column 12) as this location is indirectly stimulated by the vagus nerve, wherein said electric nerve stimulation (ENS) therapy changes a polarization of synaptic membranes in a nuclei or center of the brain of the patient as changes in polarization of synaptic membranes is a mechanism by which signals travel from nerve to nerve to and from the brain. While Boveja teaches that said method may be used in combination with pharmaceutical and non-pharmaceutical methods of treatment, including stimulating nerves in other areas of the body and including methods for treating different types of disorders (as described in lines 15-23 of column 2, lines 29-47 of column 8 and in lines 18-26 of column 18), the additional method of applying magnetic stimulation in conjunction with the above method is not expressly taught.

Epstein et al. teaches a method of treating a medical condition in a patient, said method comprising diagnosing a medical condition of a patient and administering a magnetic stimulation (MS) therapy to a body location of said patient, wherein said MS therapy comprises transcranial magnetic stimulation (TMS) (as described in the abstract and in lines 1-12 of column 13), wherein said medical condition is a neuropsychiatric disorder, wherein said magnetic stimulation (MS) therapy is administered to the nerves of the brain and wherein said MS therapy changes a polarization of synaptic

membranes in a nuclei or center of the brain of the patient and wherein said MS therapy is administered to nuclear synaptic areas including cell bodies, dendrites and pre-synaptic terminals where a membrane potential exists and an action potential does not exist thus causing stimulation in the cells and the nerves of the areas of the brain, wherein said magnetic field comprises a pulsed magnetic field (as described in lines 30-42 of column 13), wherein the step of applying a magnetic field comprises producing a current within said brain without generating a motor seizure in said patient (as described from lines 38 of column 14 through line 11 of column 15).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine a method similar to that of Boveja with a method similar to that of Epstein et al. in order to treat multiple disorders and to provide an enhanced therapy to a patient to treat their medical conditions in view of the teachings of Boveja.

Claims 25, 42, 56, 59-60, 63, 65-68 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gliner (US 2003/0074032 A1) as applied to claims 6, 27 and 51 above, in view of Fox et al. (US 2003/0050527 A1).

Gliner teaches a method of treating a medical condition of a patient, as described above, which comprises a magnetic field generator, but does not expressly teach the components such as capacitors of the magnetic field generator, that said generator comprises a plastic housing or that the method of administering a magnetic field comprises stereotaxic positioning of said magnetic field generator at a desired location.

Fox et al. teaches a method of treating a medical condition in a patient comprising diagnosing said patient and administering magnetic stimulation therapy to

said patient, wherein said method of administering magnetic stimulation therapy comprises stereotaxically positioning a magnetic coil of a magnetic generator in relation to said brain such that a magnetic field becomes focused on a selected synaptic region of said brain upon activation of said magnetic generator (as described in paragraphs [0088]-[0124]), wherein at least two coils are used in certain embodiments (as described in paragraph [0011]), wherein said magnetic stimulation therapy is performed using a magnetic stimulation subsystem comprising a configuration of switches and storage capacitors having an electrical input and an electrical output, an electrical energy source coupled to said electrical input of said configuration and at least one magnetic coil coupled to said electrical output of said configuration, wherein said pulsed magnetic field is produced by charging said storage capacitors with energy from said electrical energy source and discharging said energy from said storage capacitors into said at least one magnetic coil as said pulsed current waveform (as described in paragraphs [0006] and [0080]), wherein said at least one magnetic coil comprises wound and insulated metallic wire in a molded plastic housing (as described in paragraph [0153]) and comprises means for eliminating overheating of said coil (as described in paragraph [0080]), wherein a capacitance of said storage capacitors, a conductance of said at least one magnetic coil and a resistance of said at least one magnetic coil are regulated to control a rise time and a decay time of each pulse of said pulsed current waveform wherein said at least one magnetic coil comprises a plurality of magnetic coils arranged in different spatial planes to focus said pulsed magnetic field to precise locations in deep synaptic structures within said brain of said patient, wherein a central axis of said

at least one magnetic coil is positioned perpendicular or parallel to an imaginary line defining a synaptic region of said brain of said patient (as described in paragraphs [0062]-[0078]), wherein a ferromagnetic material is placed around said at least one magnetic coil to increase an effectiveness of said pulsed magnetic field (as described in paragraph [0066]),

It would have been obvious to one having ordinary skill in the art at the time of the invention to administer magnetic stimulation therapy similar to the method of Fox et al. in a method similar to that of Gliner in order to accurately and precisely administer a therapeutic magnetic field to highly specific regions of the brain in order to reduce the magnetic field administered unnecessarily to other portions of the brain, wherein the use of thyristors was commonly known in the art at the time of the invention and employed in transcranial magnetic stimulation devices.

Allowable Subject Matter

Claims 30, 71 and 73-75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 30, none of the prior art of record teaches or fairly suggests a method of treating a neurpsychiatric disorder in a patient comprising applying a magnetic field to the brain of said patient and administering electric nerve stimulation

therapy to the brain of the patient, wherein said magnetic field comprises a steady magnetic field.

Regarding claim 71, none of the prior art of record teaches or fairly suggests a system for providing therapeutic treatment of a neuropsychiatric disorder or other illness in a patient comprising a magnetic stimulation subsystem, an electric nerve stimulation subsystem, a computer based switching subsystem coupled to said magnetic stimulation subsystem and said electric nerve stimulation subsystem, wherein said magnetic stimulation subsystem comprises a configuration of switches and storage capacitors having an electrical input and an electrical output, an electrical energy source coupled to said electrical input of said configuration and at least one magnetic coil coupled to said electrical output of said configuration, wherein said switches comprise solid state thyristors to switch energy stored in said capacitors to said at least one magnetic coil in the form of said pulsed current waveform.

Regarding claims 73-75, none of the prior art of record teaches or fairly suggests a system for providing therapeutic treatment of a neuropsychiatric disorder or other illness in a patient comprising a magnetic stimulation subsystem, an electric nerve stimulation subsystem, a computer based switching subsystem coupled to said magnetic stimulation subsystem and said electric nerve stimulation subsystem, wherein focusing of said pulsed magnetic field within said brain of said patient is aided by placing magnetic or paramagnetic material within synaptic regions of said brain.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Epstein et al. (US 6425852 B1) teaches a method of transcranial stimulation to treat a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SL
S.L.

CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700